** NOT FOR PUBLICATION **

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MEDEVA PHARMA SUISSE A.G., et al.,	:	
Plaintiffs,	:	Civil Action No. 10-cv-4008
v.	:	OPINION
PAR PHARMACEUTICAL, INC., et al.,	:	
Defendants.	:	

Plaintiffs Medeva Pharma Suisse A.G. ("Medeva"), Warner Chilcott Pharmaceuticals, Inc. and Warner Chilcott Company, LLC ("Warner Chilcott,") (collectively referred to as "Plaintiffs") bring this patent infringement action alleging, inter alia, infringement of U.S. Patent No. 5,541,170 ("the '170 patent") by Defendants Par Pharmaceutical, Inc. ("Par") and Emet Pharmaceuticals, LLC ("Emet," collectively referred to as "Defendants") in submitting their Abbreviated New Drug Application ("ANDA") to market a generic version of the Asacol® drug product, which is approved for the treatment of an inflammatory disease of the large intestine. Asacol® is currently produced by Warner Chilcott and covered by the '170 patent owned by Medeva.

Before the Court is the parties' request that the Court construe the following terms in dispute within the claims of the '170 patent: 1) "whereby the dosage form

releases the 5-amino-salicylic acid, salt or ester to the right side of the colon" / "whereby the 5-amino-salicylic acid is released to the right side of the colon"; 2) "a layer which is insoluble in gastric juice and in intestinal juice below pH 7 but soluble in colonic intestinal juice"; and 3) "said solid oral dosage form being coated so as to release the 5-amino-salicylic acid, salt or ester to the right side of the colon." A Markman hearing was held on October 18, 2011. The Court has considered the written submissions of the parties, along with the certifications and testimony of Plaintiffs' expert, Dr. Roland Bodmeier, and Defendants' expert, Dr. Edmund Elder, Jr.. The Court shall construe the terms in the context of the asserted claims as set forth herein.

I. BACKGROUND

In light of the protracted prosecution history relating to the '170 patent, and the parties' reliance upon various aspects of that history, the Court includes a lengthier than usual background section in this Opinion. That said, this section provides only an overview and there are specific aspects of the prosecution history that are addressed, where relevant, in the body of the Opinion.

A. The '170 Patent

The '170 patent, entitled "Orally Administrable Pharmaceutical Compositions," claims certain pharmaceutical compositions that allow selective administration of a pharmacologically active agent to the large intestine (also known as "the colon"). The claims of the '170 patent include Asacol® and its methods of production.

The active ingredient of Asacol® is mesalamine (5-amino-salicylic acid, or 5-ASA). Mesalamine has been used since the 1970s in treating diseases or ailments

of the colon, especially ulcerative colitis or Crohn's disease. Ulcerative colitis begins at the rectum and then progresses backwards through the colon, in some patients all the way to the beginning of the ascending colon. Prior to the '170 patent invention, mesalamine was administered in the form of the drug substance sulphasalazine ("SASP"), a complex drug substance that is broken down to mesalamine and sulphapyridine by colonic bacteria. Although SASP was effective, patients often suffered serious side effects. Realizing that the sulphapyridine was responsible for such side effects, pharmaceutical companies directed efforts toward developing a way of delivering mesalamine to the colon that retained SASP's effectiveness but avoided its side effects. However, the prior art to the '170 patent did not achieve such a goal, and orally administered dosage forms were generally absorbed into the blood stream in the stomach or small intestine before reaching the colon.

The '170 patent describes a solid oral dosage form containing mesalamine, coated with an anionic polymer (or polymers) designed to remain intact until reaching the colon, and to release the mesalamine to the colon without substantial leaching before reaching the colon. Based in part on the fact that the pH in the human gastrointestinal tract increases from the stomach to the colon, by which point the pH reaches about 7, the inventors found a formula for the layer that is insoluable below pH 7, but soluble above pH 7. Once the dosage form reaches the colon, the coating layer begins to dissolve, and accordingly mesalamine is administered to the colon.

B. Prosecution History

On July 28, 1982, following a clinical trial demonstrating that the claimed

formulation was as effective as SASP in treating ulcerative colitis, the inventors filed an application for a U.S. patent (No. 82/000235). After several continuation applications (No. 06/482,331, No. 06/735,727, No. 07/584,386, No. 07/858,449 and No. 08/032,167), the inventors filed a divisional application (No. 08/401,696) on March 10, 1995, which ultimately led to the issuance of the '170 patent on July 30, 1996. Meanwhile, the patent application of No.08/032,167 was followed by another continuation application (No.08/448,300), for which the Patent Office issued U.S. Patent No. 5,541,171 ("the '171 patent").[1] In filing the divisional application, which separated out the claims ultimately incorporated into the '170 patent, the patentees sought to patent broader claims than those ultimately incorporated into the '171 patent.

In short, the '170 and '171 patents flow from the same earlier continuation applications. The following chart illustrates the history of these related patents.

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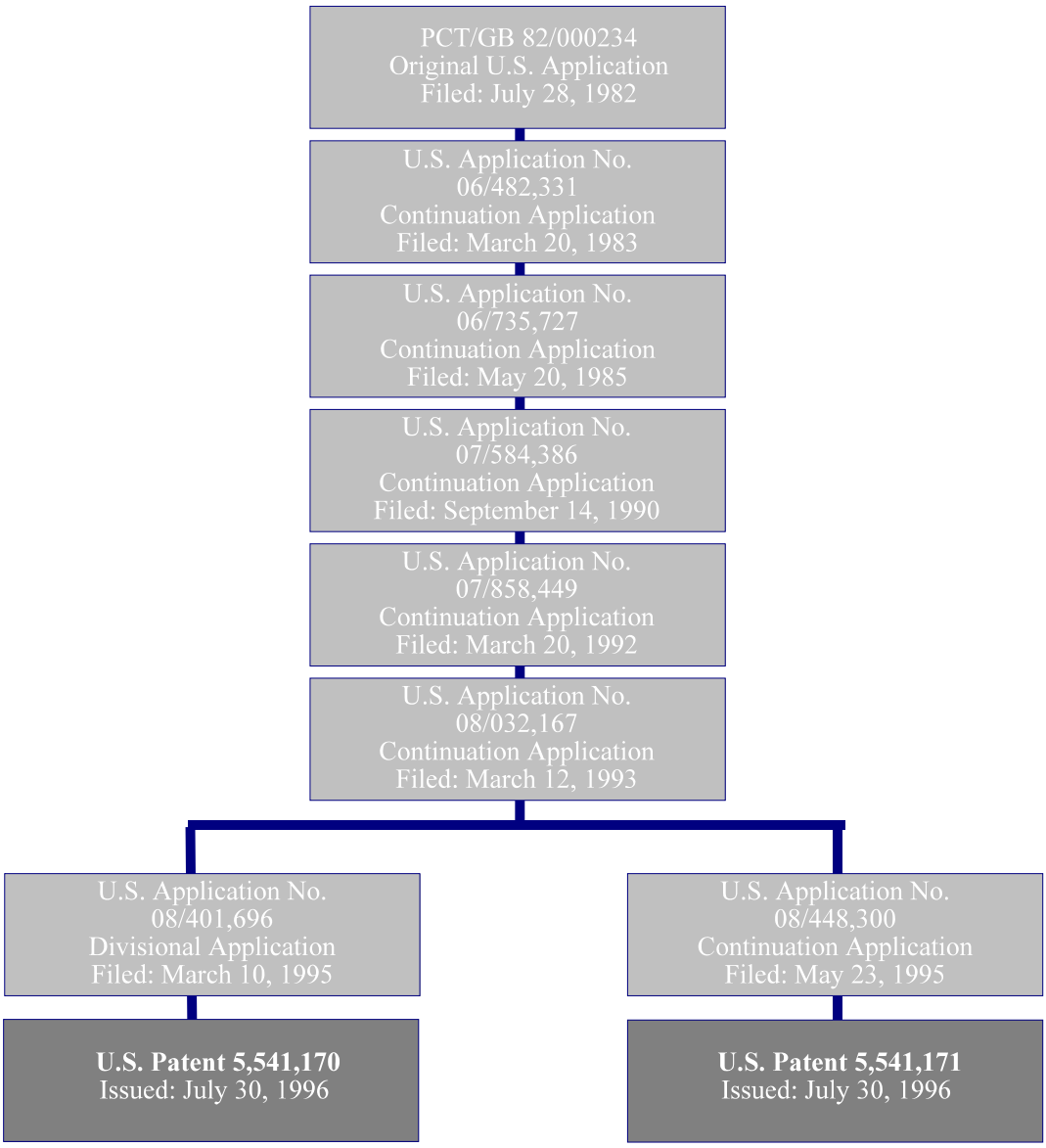
[1] Even though Plaintiffs made no claim that Defendants' ANDA infringed upon the '171 patent, Defendants filed a counterclaim for declaratory judgment regarding the validity of the '171 patent. This Court dismissed it on the ground that Defendants lack standing to bring the counterclaim based upon Plaintiffs' offering of a covenant not to sue Defendants on the '171 patent. Medeva Pharma Suisse A.G. v. Par Pharm., Inc., 774 F.Supp.2d 691, 699 (D.N.J. 2011), aff'd, 2012 U.S. App. LEXIS 1516 (Fed. Cir. Jan. 25, 2012).



The prosecution history for the '170 patent, and the related '171 patent, is extensive, spanning over fourteen years. As noted above, the use of 5-ASA topically on the colon was a familiar treatment; it was the patentees' ability to ensure that the treatment did not leach out before reaching the colon that made their invention unique. Hence, throughout the prosecution of the patent, the patentees spent significant time

distinguishing their formulation from the prior art. In this connection, the patentees further emphasized the high organ specificity of their coating and dosage form, and that the mesalamine was "dumped" into the colon, rather than consistently released in small amounts prior to, throughout, and following the colon. The several continuation applications were occasioned by the patentees' failure to convince a given examiner that their invention was not obvious to one familiar with the prior art. Through their perseverance, the patentees were ultimately able to convince the examiners that their patents should be issued.

There are three types of prior art distinguished by the patentees throughout the prosecution history that are relevant here. One prior art was the use of a coating comprised of mixtures of Eudragit S & Eudragit L, in certain thicknesses, which thickness was insufficient to ensure that the 5-ASA did not leach out before reaching the colon. Contrary to the prior art, the patentees contended that their coating was thicker and, consequently, did not dissolve too early in the intestinal tract. In this connection, the patentees also noted that they used coatings comprised only of Eudragit S, as opposed to both S & L, along with other polymers.

Another prior art was the use of a resin in the coating formulation that effected a time release-based delivery. Rather than employing a time-release carrier system for delivering the drug, the patentees' formulation was pH-dependent; the patentees' coating would not dissolve until it reached the area of the intestines that contains pH 7 fluids. The patentees further argued that a pH-based carrier system is more reliable because release of the drug from a time-release system may vary from two to five hours

and, thereby, release too early during the digestive process before reaching the colon.

Finally, the patentees distinguished all prior oral administrations of 5-ASA as not specified to prevent release of 5-ASA before reaching the colon.

C. Comparing the '170 and '171 patents

As noted, the '170 and '171 patents share the same parent applications, those filed from 1982 through 1993. However, per the divisional application filed in 1995, the patentees split their application into two. Divisional Application No. 08/401,696 became the application for what was ultimately issued as the '170 patent, and Continuing Application No. 08/448,300 became the application for what was ultimately issued as the '171 patent.

Generally, divisional applications are submitted by applicants where the PTO has imposed a restriction requirement on the applicants' original application. "An examiner enters a restriction requirement when he determines that the application includes claims to independent and distinct inventions." 4A-12 Chisum on Patents § 12.04; see 35 U.S.C. § 121 ("If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions."). Thereafter, the applicant must elect one of the inventions to pursue. See 37 C.F.R. § 1.142. After the applicant has elected one of the inventions, the patent examiner will withdraw from further consideration all claims for the nonelected inventions. 4A-12 Chisum on Patents § 12.04. An applicant who wishes to pursue what was withdrawn "may file a divisional application claiming the nonelected inventions ...." Id.

A key difference between the '171 patent and the '170 patent here is that the former expressly excludes coating mixtures of Eudragit S & Eudragit L whereas the latter does not. Further, as noted, the patentees sought broader claims in the divisional application that resulted in the '170 patent.

D. Disputed Claims

The parties present three disputed terms for construction in claims1, 6 and 7 of the '170 Patent. The claim language reads:[2]

Claim 1

1. An orally administrable pharmaceutical composition for selectively administering 5-amino-salicylic acid, or pharmaceutically acceptable salt or ester thereof, to the large intestine, comprising a solid oral dosage form containing a pharmaceutically effective amount for the treatment of ulcerative colitis or Crohn's disease of the colon of said 5-amino-salicylic acid, salt or ester, said solid oral dosage form being coated with a layer which is insoluble in gastric juice and in intestinal juice below pH 7 but soluble in colonic intestinal juice, whereby the dosage form releases the 5-amino-salicylic-acid, salt or ester to the right side of the colon.

Claim 6

6. A method for treating ulcerative colitis or Crohn's disease of the colon comprising orally administering to a person suffering therefrom the composition of claim 1 whereby the 5-amino-salicyclic acid is released to the right side of the colon.

Claim 7

7. An orally administrable pharmaceutical composition for selectively administering 5-amino-salicylic acid, or pharmaceutically acceptable salt or ester thereof, to the large intestine, comprising a solid oral dosage form containing a pharmaceutically effective amount for the treatment of ulcerative colitis or Crohn's disease of the colon of said 5-amino-salicylic acid, salt or ester, said solid oral dosage form being coated so as to release the 5-amino-salicylic acid, salt or ester to the right side of the colon.

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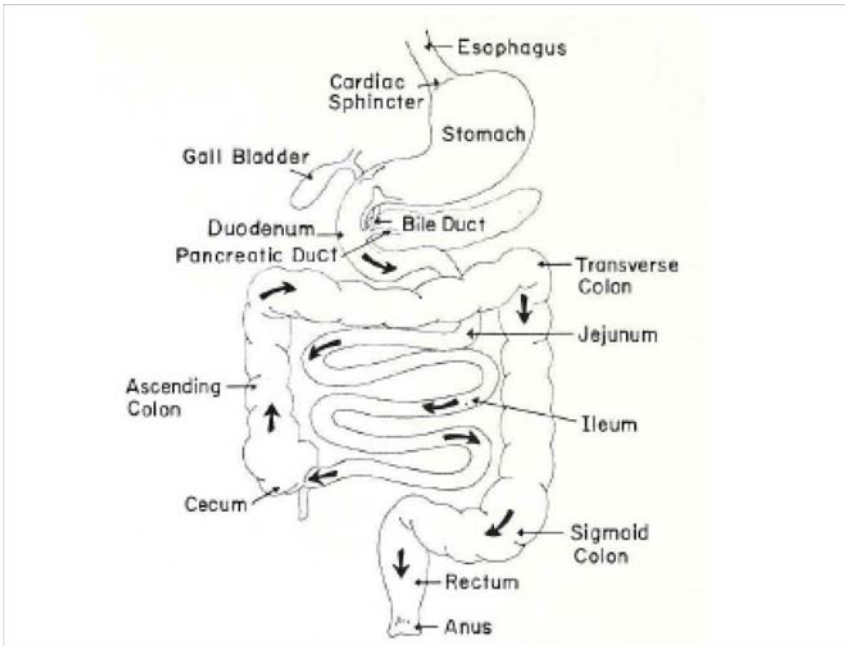
[2] The disputed terms are highlighted.

To understand the parties' proposed constructions, a basic schematic of the gastrointestinal tract is useful.



Bodomeier Decl. dated Jun. 2, 2011 at ¶ 11.

As this schematic illustrates, the ileum precedes the cecum (also referred to as the caecum) and the ascending colon. Both parties agree that, in common parlance, "colon" refers to the area beginning with the ascending colon (or "right side of the colon") and does not include the ileum. This area, the ascending colon, is also referred to by the parties as the "large intestine." One of the parties' key claim construction disputes is whether the patentees taught that their formulation of 5-ASA would release in both the ileum and the ascending colon. To be clear, the parties refer in their proposed constructions specifically to the distal ileum (or terminal ileum), which is the latter most part of the ileum adjacent to the cecum. The patentees used distal ileum

and terminal ileum interchangeably throughout the prosecution history. For ease of reference, the Court will use the term distal ileum except when quoting prosecution history statements, the parties' briefs, or proposed constructions that refer to the terminal ileum.

The parties' proposed constructions of the disputed terms are as follows:

Disputed Terms	Plaintiffs' Construction	Defendants' Construction
A layer which is insoluble in gastric juice and in intestinal juice below pH 7 but soluble in colonic intestinal juice (Claim 1)	The dosage form is coated with at least one layer that has sufficient thickness so that the coating does not *fully* dissolve or disintegrate in gastric juice and in intestinal juice below pH 7, but does dissolve or disintegrate in colonic intestinal juice.	None of the layer dissolves (i.e., the layer is insoluble) in aqueous medium below pH 7 but the layer does dissolve below pH 7.5. This excludes layers containing mixtures of Eudragit S and Eudragit L.
Whereby the dosage form releases the 5-amino-salicylic-acid, salt or ester to the right side of the colon (Claim 1)	Substantially all of the drug leaves the dosage form in the distal part of the small intestine or the ascending colon.	The coating reliably releases all of the active ingredient contained in the dosage form to the right side of the colon (i.e., the ascending colon, and not the terminal ileum).
Whereby the 5-amino-salicylic-acid is released to the right side of the colon (Claim 6)	(same)	(same)
Said oral dosage form being coated so as to release the 5-amino-salicylic-acid, salt or ester to the right side of the colon (Claim 7)	Substantially all of the drug leaves the dosage form in the distal part of the small intestine or the ascending colon.	The coating is insoluble below pH 7, i.e. Eudragit S, and thereby reliably releases all of the active ingredient contained in the dosage form to the right side of the colon (i.e., the ascending colon, and not the terminal ileum).

II. LEGAL STANDARDS

A. General Claim Construction Standard

Claims define the scope of the inventor's right to exclude. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005). Claim construction determines the correct claim scope, and is a determination exclusively for the court as a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 978-79 (Fed. Cir. 1995) (en banc). Indeed, the court can only interpret claims, and "can neither broaden nor narrow claims to give the patentee something different than what it has set forth" in the specification. E.I. Du Pont de Nemours v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir. 1988).

This interpretive analysis begins with the language of the claims, which is to be read and understood as it would be by a person of ordinary skill in the art. Dow Chem. Co. v. Sumitomo Chem. Co., 257 F.3d 1364, 1372 (Fed. Cir. 2001); see also Markman, 52 F.3d at 986 ("The focus [in construing disputed terms in claim language] is on the objective test of what one of ordinary skill in the art at the time of invention would have understood the terms to mean"); Phillips, 415 F.3d at 1312-13. In construing the claims, the court may examine both intrinsic evidence (e.g., the patent, its claims, the specification and prosecution history) and extrinsic evidence (e.g., expert reports, testimony and anything else). Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999). However, claims may not be construed with reference to the accused device, which means that the court may

not construe a claim to fit the dimensions of the accused device, thus to prejudice the claim construction by "excluding or including specific features of the accused device." Wilson Sporting Goods Co. v. Hillerich & Bradsby Co., 442 F.3d 1322, 1330 (Fed. Cir. 2006). Nevertheless, the knowledge of the accused device before or during claim construction is not only permissible, but also necessary to claim construction because it "supplies the parameters and scope of the infringement analysis." Id. at 1330-31; Lava Trading Inc. v. Sonic Trading Mgmt., 445 F.3d 1348, 1350 (Fed. Cir. 2006).

In interpreting the disputed terms, it is well settled that the Court should look first to the intrinsic evidence. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Generally, words in patent claims are given their "ordinary and accustomed meaning as understood by one of ordinary skill in the art" at the priority date of the patent application. Dow Chem., 257 F.3d at 1372; K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1362 (Fed. Cir. 1999). The claims must be construed objectively in the context of both the particular claim and the entire patent because "the claims themselves provide substantial guidance as to the meaning of particular claim terms," and claim terms are normally used consistently throughout the patent. Phillips, 415 F.3d at 1313-14.

Moreover, courts are instructed to look to the specification, which is a written description of the invention. "[C]laims 'must be read in view of the specification, of which they are a part.'" Id. at 1315 (quoting Markman, 52 F.3d at 979). Indeed, the specification is perhaps "the single best guide to the meaning of a claim term" due to its statutory requirements of being in "full, clear, concise, and exact terms." Id. at

1316; see 35 U.S.C. §112. "The specification acts as a dictionary when it expressly" or implicitly defines terms used in the claims. Markman, 52 F.3d at 979. Thus, it effectively limits the scope of the claim. On Demand Mach. Corp. v. Ingram Industries, Inc., 442 F.3d 1331, 1340 (Fed. Cir. 2006). Due to its nature, "the specification 'is always highly relevant to the claim construction analysis. Usually it is dispositive." Id. (quoting Vitronics Corp., 90 F.3d at 1582).

Extrinsic evidence includes all evidence external to the patent and prosecution history, i.e., expert and inventor testimonies, dictionaries, and learned treaties. Markman, 52 F.3d at 980. It is considered only where the intrinsic evidence does not provide a sufficient description to resolve ambiguities in the scope of the claim. See Vitronics, 90 F.3d at 1583; Johnson Worldwide Assocs. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999). However, the Federal Circuit cautioned, in Phillips, that dictionary definitions should not be used to interpret patent claim terms in a manner that is divorced from the context and description of the invention in the specification. Phillips, 415 F.3d at 1321. The Phillips court reasoned that because of the nature of the patent claims, the dictionary definitions, as extrinsic evidence, are usually less reliable than the patent documents themselves in establishing the ordinary meaning of a claim term. Id. at 1314; Toro Co. v. White Consol. Indus., 199 F.3d 1295, 1299 (Fed. Cir. 1999). Ultimately, extrinsic evidence cannot be used to vary or contradict claim terms when their meanings are discernible from intrinsic evidence. C. R. Bird, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004).

B. Disclaimers and Disavowals

"[I]n certain cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." Ventana Medical Systems, Inc. v. Biogenex Laboratories, Inc., 473 F.3d 1173, 1181 (Fed. Cir. 2006) (quoting Phillips, 415 F.3d at 1316) (internal citations omitted). In such cases, the Federal Circuit interprets the claim more narrowly than it otherwise would in order to give effect to the patentee's intent to disavow a broader claim scope. Id. (citing Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1319-20 (Fed. Cir. 2006); SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1342-44 (Fed. Cir. 2001).

However, pointing solely to "general statements by the [patentee] indicating that the invention is intended to improve upon prior art" will not demonstrate that the patentee intended to "disclaim every feature of every prior art device discussed in the 'BACKGROUND ART' section of the patent." Id. See also Thorner v. Sony Computer Entertainment America LLC, 669 F.3d 1362 (Fed. Cir. 2012) ("Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal.") (quoting Epistar Corp. v. Int'l Trade Comm'n, 566 F.3d 1321, 1335 (Fed. Cir. 2009)).

Moreover, the Federal Circuit has found it "particularly important not to limit claim scope based on statements made during prosecution '[a]bsent a clear disavowal or contrary definition." Digital-Vending Services Intern., LLC v. University of Phoenix, Inc., 672 F.3d 1270, 1273 (Fed. Cir. 2012) (citing August Tech. Corp. v. Camtek, Ltd., 655 F.3d 1278, 1286 (Fed. Cir. 2011) (quoting Home Diagnostics, Inc. v. LifeScan, Inc., 381 F.3d 1352, 1358 (Fed. Cir. 2004)). The reason for such a

stringent rule is "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." Id. (quoting Phillips, 415 F.3d at 1317).

C. Related Applications

Generally, "statements made by the inventor during continued prosecution of a related patent application can, in some circumstances, be relevant to claim construction." Ventana, 473 F.3d at 1184 (citing Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1349 (Fed. Cir. 2004)). This is particularly so where "the prosecution history of one patent is relevant to an understanding of the scope of a common term in a second patent stemming from the same parent application." Multi-Tech, 357 F.3d at 1349. Similar to statements made by the patentee during the prosecution of an ancestor application, "statements made during the continued prosecution of a sibling application may inform the meaning of the claim language by demonstrating how the inventor understood the invention." Ventana, 473 F.3d at 1184 (citing Phillips, 415 F.3d at 1317). Moreover, the "prosecution history of a related patent application may inform construction of a claim term, when the two applications are directed to the same subject matter and a clear disavowal or disclaimer is made during prosecution of the related application." TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc., 529 F.3d 1364, 1371 (Fed. Cir. 2008).

Prosecution history estoppel applies with equal force to divisional applications. See Desper Prods., Inc. v. QSound Labs, Inc., 157 F.3d 1325, 1339 n. 6 (Fed. Cir.

1998) (relying on common parent application to construe claims in both a divisional and a related application). However, "[w]hen the applicant is seeking different claims in a divisional application, estoppel generally does not arise from the prosecution of the parent." Biogen, Inc. v. Berlex Laboratories, Inc., 318 F.3d 1132, 1140 (Fed. Cir. 2003).

III. DISCUSSION

The parties' claim construction arguments relate to two claim terms: the "release to the right side of the colon" language found in claims1, 6, and 7; and the "insoluble in gastric juice" language found in claim 1. In addition, Defendants further argue, via the doctrine of prosecutory estoppel, that the patentees disclaimed mixtures of Eudragit S and Eudragit L. Finally, Defendants contend that a pH limitation should be read into claim 7 although that claim includes no such express limitation. I address each of these issues in turn.

A. Releasing "to the right side of the colon"

Each of the disputed claims speaks of releasing 5-ASA "to the right side of the colon." As explained above, 5-ASA must be applied topically, thus, the precise placement of the formulation onto the colon's surface is central to the patentees' invention. In this connection, the parties dispute whether "to the right side of the colon" should be construed to mean releasing within the distal ileum or the ascending colon (Plaintiffs' view) or, alternatively, to release only within the ascending colon and not within the distal ileum (Defendants' view). In addition, the parties dispute what amount of the drug must be released. Plaintiffs construes the claim language

to mean that "substantially all" (at least 80%) of the drug must be released whereas Defendants argue that "all" (near 100%) of the drug must be released to the right side of the colon.

The parties proposed constructions are as follows:

Claim Language	Plaintiffs' Construction	Defendants' Construction
Whereby the dosage form releases the 5-amino-salicylic acid, salt or ester to the right side of the colon (Claim 1) / Whereby the 5-amino-salicylic acid is released to the right side of the colon (Claim 6)/ Said oral dosage form being coated so as to release the 5-amino-salicylic-acid, salt or ester to the right side of the colon (Claim 7)	Substantially all of the drug leaves the dosage form in the distal part of the small intestine or the ascending colon.	The coating reliably releases all of the active ingredient contained in the dosage form to the right side of the colon (i.e., the ascending colon, and not the terminal ileum).

1. Distal Ileum

Defendants argue that their construction comports with the ordinary meaning of "right side of the colon." First, they note that the right side of the colon (also known as ascending colon) is a part of the large intestine, and therefore the small intestine is not included by definition. Furthermore, because the patentees never expressly defined "the colon" to include the distal part of the small intestine, Defendants contend that Plaintiffs' construction is inconsistent with the claim language. Citing Merck & Co. v. Teva Pharms. USA, 395 F.3d 1364, 1370 (Fed. Cir. 2005), for the proposition that "[w]hen a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning,

he must clearly express that intent in the written description," Defendants argue that the patentees did not clearly express an intent to redefine the phrase "right side of the colon."

In support of their argument that the patentees did not intend release in the distal ileum to be a part of the invention, Defendants point to an example in the specification. In Example IV in the specification, six capsules were given to each of six patients (36 capsules in total) and their integrity was tracked over time via X-ray analysis. Four of the capsules broke in the distal ileum and 23 broke at the colon. According to Defendants, the results of the Example show that the patentees considered the invention exemplified by the 23 capsules that "remained intact after oral ingestion until they reached the right side of the colon when the capsule broke releasing its contents," and not the four capsules that broke in the distal ileum. '170 patent, col. 7 at 16-19.

By contrast, Plaintiffs contend that the intrinsic evidence confirms that the claim limitation of "release to the right side of the colon" encompasses liberation of the drug in the distal portion of the small intestine. For example,

- Example IV—the same example relied upon by Plaintiffs— reports that the capsules "remained intact in the stomach and proximal small bowel [upper small intestine]" and then broke either in the "distal ileum" or the colon. '170 patent col. 7 at 3-7.
- A September 26, 1984 Amendment explains that the patentees' preference for a coating thickness between 60 and 160 microns as providing for a coating "which would reliably break in the terminal ileum or in the proximal large intestine (ascending caecum and ascending colon usually)."

- A March 14, 1988 Response states that "[t]his unit dosage form [of the invention] has been developed to carry the [mesalamine] to the last portion of the small intestine or the first portion of the colon before the coating disintegrates or dissolves, in order to provide an effective dose of [mesalamine] to the colon for the treatment of ulcerative colitis or Crohn's disease therein."

- A November 17, 1995 Responsive Amendment states that "[t]he composition of the claimed invention is embodied in the product Asacol®" and then cites literature showing Asacol®, an embodiment of the '170 patent, "break[ing] up in the terminal ileum or ascending colon."

Plaintiffs' Opening Br. at 12-13 (citations omitted).

In addition, Plaintiffs argue that the intrinsic evidence also describes the preferred embodiment of the claims—a solid oral dosage form coated with a thick Eudragit S coating—as releasing the drug in the distal ileum in order to provide therapy throughout the colon. Because Defendants construe claims to exclude release in the distal ileum, Plaintiffs reason that it is contrary to the intrinsic evidence, and would improperly exclude the preferred embodiment from the claims. As such, Defendants' construction must be, according to Plaintiffs, rejected, because "[a] claim interpretation that reads out a preferred embodiment is rarely, if ever, correct and would require highly persuasive evidentiary support." Id. at 13 (quoting Virtonics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996)).

More importantly, Plaintiffs emphasize that Defendants' construction is clearly contradicted by the expressed definition of the claim term provided by the inventors in connection with a related application. Plaintiffs note that in a continuation application (the '300 application) that ultimately led to issuance of the '171 patent, the patentees expressly stated that "the claim limitations of remaining 'intact until

it reaches the colon' and 'release to the right side of the colon' embrace breaking up in the terminal ileum or ascending colon and releasing in the distal part of the small intestine." Id. at 14 (quoting Ainsworth Ex. F at 7). Accordingly, Plaintiffs maintain that Defendants' proposal to exclude such release from the claims is inconsistent with the claim language and the intrinsic evidence.

Furthermore, Plaintiffs cite to the declaration of their expert witness, Dr. Bodmeier. In his declaration, Dr. Bodmeier explained that because coating dissolution and tablet disintegration are not instantaneous events, it may be preferable to design dosage form to disintegrate shortly before entry into the right side of the colon in the distal portion of the small intestine. Bodmeier Decl., ¶ 29. Because the best way to deliver the drug to the very beginning of the right side of the colon (around the cacum) may be to release the drug near the end of the small intestine (e.g., in the distal ileum), Plaintiffs claim that a skilled artisan would understand that release to the right side of the colon includes release in the distal ileum .

Because the parties do not dispute that the ordinary and customary meaning of the "right side of the colon" does not include the distal part of the small intestine, the issue before the Court is whether the patentees clearly expressed their intention in the patent or prosecution history to either: (a) include the distal part of the small intestine in the definition of "right side of the colon;" or (b) by claiming that the drug will release "to" the right side of the colon, expressed their intention that the drug

release in the distal ileum in order to facilitate topical application in the ascending colon, as Dr. Bodomeier suggests.

As an initial matter, I reject the argument that the patentees acted as their own lexicographer by specially defining "right side of the colon" in the specification or the prosecution history. There is no language in the specification that can be read as clearly setting forth a special definition of either colon or "right side of the colon." Indeed, the only reference to the distal ileum in the specification is in Example IV, and that example distinguishes between the distal ileum and the colon: "In a few patients occasional capsules broke in the distal ileum (4 of 36) but after 12 hours 32 capsules had reached the colon and of these, 23 had broken at this site." '170 Patent, col. 7 at 4-7 (emphasis added). See also File History, 06/482,331 App., Sept. 26, 1984 Amendment at 9 (Ainsworth Decl., Exh. J at WC373) ("[T]he coating would reliably break in the terminal ileum or in the proximal large intestine (ascending caecum and ascending colon usually).") (emphasis added).

However, the claim language envisions an initial breaking or disintegration of the coating layer in the distal ileum so as to release the 5-ASA in the colon. While, on the one hand, the patentees describe the invention in the specification as "remain[ing] intact until it reaches the colon," see e.g., '170 Patent, col. 4 at 20; id. at 4:30; id. at 4:63, the broadly worded claim language of releasing "to" the colon encompasses the initial dissolution in the distal ileum in order to ensure that the drug is topically applied on the colon's surface. Moreover, the Federal Circuit has repeatedly held it inappropriate to read limitations from the specification into the

claim. See e.g., Thorner, 669 F.3d at 1366 ("We do not read limitations from the specification into claims ...."); Phillips, 415 F.3d at 1315, 1323 ("The claims are read in context with the specification, but limitations from the specification should not be read into the claims."). And, "[i]t is the claims that define the metes and bounds of the patentee's invention." Thorner, 669 F.3d at 1367.

It is true that for all the embodiments of the invention discussed in the specification, it is anticipated that the "dissolution or disintegration [will] not occur until entry of the coated dosage form into the colon." Id. col. 4 at 1-3. Nevertheless, "[i]t is . . . not enough that the only embodiments, or all of the embodiments, contain a particular limitation." Thorner, 669 F.3d at 1366. See also Kara Technology Inc. v. Stamps.com Inc., 582 F.3d 1341 (Fed. Cir. 2009) ("[W]e have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.") For a limitation to be imported from the specification into a claim, the specification must describe the "present invention" or otherwise make explicit that all contemplated embodiments of the claim contain the limitation. Id. Indeed, this was the case in SciMed, 242 F.3d at 1341, a case relied upon by Defendants. Unlike SciMed, the specification here makes no pronouncement that all contemplated embodiments will break or release in the colon.

In addition, Example IV in the specification supports my construction of the "release to the right side of the colon" language. As noted, in that example, the patentees described the capsules as occasionally breaking "in the distal ileum ...."

'170 Patent, col. 7 at 5. I note, however, that the Example IV language suggests that occasional rather than frequent breaking in the distal ileum was contemplated.

The prosecution history of the '170 patent further supports my construction. There is language in the early prosecution history of both the '170 and '171 patents, before the patent applications were divided, that embraces release in the distal ileum. During prosecution of the '331 application, in 1984, the patentees stated that they "obtained a consistent behavior of the coating would reliably break in the terminal ileum or in the proximal large intestine (ascending caecum and ascending colon usually)." File History, 06/482,331 App., Sept. 26, 1984 Amendment at 9 (Ainsworth Decl., Exh. J at WC373). Similarly, in connection with the '727 application, the patentees stated that the "dosage form has been developed to carry the 5-ASA to the last portion of the small intestine or first portion of the colon, before the coating disintegrates or dissolves ...." File History, 06/737,727 App., Mar. 14, 1988 Response and Presentation of Evidence Under Rule 12 at 3 (Ainsworth Decl., Exh. K at WC446).

There is also language embracing initial dissolution in the distal ileum in the divisional application that ultimately resulted in the issuance of the '170 patent, although that language refers specifically to the preferred embodiment Asacol®. In the prosecution of that application, the patentees stated that Asacol® "has been shown to break up in the terminal ileum or ascending colon," File History, 06/401,696 App., Nov. 17, 1995 Responsive Amendment at 4-5 (Ainsworth Decl., Exh. E at

WC132-33), and that it "dissolves in the terminal ileum." Id., Mar. 13, 1996 Responsive Amendment at 4 (Ainsworth Decl., Exh. O at WC180).[3]

Read together, these statements from the prosecution history support a construction of the "release to the right side of the colon" claim language that includes release in the distal ileum.[4] That the patentees also intermittently used the phrase "release . . . in the colon" to describe the drug's release profile in parts of the specification and prosecution history does not alter my construction. For example, Defendants point to language in the specification distinguishing prior art as "not provid[ing] for release of 5-ASA only in the colon." '170 patent, col. 3: 59-60 (emphasis added). While this isolated statement might suggest that the patentees used "in the colon" and "to the colon" interchangeably, by reading the sum of the prosecution history it is clear that their focus was topical application of the 5-ASA to the colon wall whether the dosage form began to dissolve in the distal ileum or the ascending colon.

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[3] Defendants argued at oral argument that Asacol® is not a preferred embodiment because it did not exist at the time of the original 1984 patent application. Even so, Asacol® utilizes a coating of neat Eudragit S, which Defendants do not contest falls within the bounds of the claims. Moreover, Defendants appear to contend that the '170 patent claims should be limited to Eudragit S formulations by arguing that the patentees disavowed mixtures of Eudragit S and Eudragit L.

[4] Plaintiffs further point to a clear and unequivocal statement regarding release to the right side of the colon made during the post-division related patent application (the '300 application) for the '171 patent. In light of the aforesaid statements made in connection with the '170 patent prosecution, I need not rely on this statement in the related Patent's'171 patent file history.

The Court does not wholesale adopt Plaintiffs' construction, however. In construing the claims, "[t]he judge's task is not to decide which of the adversaries is correct. Instead, the judge must independently assess the claims, the specification, and if necessary the prosecution history, and relevant extrinsic evidence, and declare the meaning of the claims." Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1556 (Fed. Cir. 1995); MEMS Technology Berhad v. International Trade Com'n, 447 Fed.Appx. 142, 153 (Fed. Cir. Jun. 3, 2011) (same). Following that dictate here, I adopt a slightly more constrained construction.

Plaintiffs' proposed construction is: "Substantially all of the drug leaves the dosage form in the distal part of the small intestine or the ascending colon." The problem with this construction is that it fails to take into account, as reflected by a careful reading of claim language, specification, and prosecution history, that the patentees contemplated that the drug would most often release in the colon and that, much less often, the drug would begin to leave the dosage from while still in the distal ileum. Moreover, Plaintiffs' construction also fails to take into account that the prosecution history statements focus on the dissolution beginning in the distal ileum so that the 5-ASA leaves the dosage form in the colon. The Court appreciates that the invention's function in the body is not so precise that the dosage form will never break or begin to release in the distal ileum. Nevertheless, the prosecution history strongly suggests that the invention was intended to primarily break and/or release in the colon even where some dissolution or disintegration of the coating began in the distal ileum.

Also supporting my view is that the patentees repeatedly sought to distinguish the extensive prior art by focusing on the invention's tendency to release much later in the digestive system than the prior art. In the specification, for example, the patentees distinguish prior art using various coating materials on 5-ASA capsules as unable "to prevent release of 5-ASA until the colon." '170 patent, col. 3:23-25 (emphasis added). See also id. at 3:57-60 (distinguishing time-release capsules as not providing for "reliable release of 5-ASA only in the colon) (emphasis added). Most notably, after distinguishing additional prior art based on the use of granules versus a capsule, and the thickness of the coating used, the specification describes the invention as follows:

> The Inventors have now found that 5-ASA reliably can be administered specifically to the large intestine, especially the colon, by simply coating a solid oral dosage form with a sufficient thickness of a partly methyl esterified methylacrylic acid polymer which does not dissolve in aqueous medium below pH 7 but does dissolve below pH 7.5. This carrier system differs from those previously disclosed in relation to 5-ASA in that dissolution or disintegration does not occur until entry of the coated dosage form into the colon. In particular, there is substantially no leaching out of the 5-ASA downstream of the colon in the normal patient.

Id., col. 3:61 - 4:4 (emphasis added). By distinguishing prior art as unable to reliably dissolve in the colon, without leaching out downstream of the colon, the patentees contemplated that, on most occasions, the drug would break up in the colon and not the distal ileum. The patentees' use of the modifiers "reliably," as in the "5-ASA reliably can be administered specifically to the large intestine," and "substantially," as in "there is substantially no leaching out . . . downstream," further support my

construction that the drug form only occasionally begins dissolution prior to entering the ascending colon. Moreover, the specification emphasizes the "high organ specificity" of the "present invention," id., col. 5:50-52, which further clarifies that the dosage form is designed to most often begin dissolution and/or break in the ascending colon.

Finally, the Court has reviewed the extensive, fourteen-year prosecution history of the '170 patent. While it would take too many pages to recount the history in more detail here, the Court notes that much of the file is spent distinguishing the prior art on fine points and defending the patentees' contention—following multiple rejections—that the invention reliably releases in a manner that ensures topical delivery to the colon. There are smatterings of phrases throughout the history that reference release of the drug in the terminal or distal ileum, discussed infra, however, those statements are farther and fewer between than Plaintiffs suggest. In reading the file wrapper as a whole, one is left with the firm impression that the patentees did not anticipate the drug often or regularly dissolving or releasing in the distal ileum.[5] Cf. Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1379 (Fed. Cir. 2008) (explaining that the "totality of the prosecution history informs the disavowal inquiry") (quoting Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1326 (Fed. Cir. 2002)) (internal quotation marks omitted). Accordingly, the Court's construction

[5] In this regard, the Court notes that the parties did not provide the Court with the entire file wrapper for the '170 patent perhaps due to the lengthy prosecution period. The Court reviewed those portions provided by the parties.

(set forth below) will take into account the limited circumstances in which the patentees envisioned the dosage form beginning to dissolve or break in the distal ileum. The construction will further take into account that the drug will not be released prior to reaching the distal ileum. In my view, this sort of construction best reflects the high organ specificity of the invention and the patentee's focus on "dumping" the drug into the colon for topical treatment.

2. The amount to be released

I adopt Plaintiffs' proposed construction that "substantially all" as opposed to "all" of the 5-ASA must be released in the colon.[6] Defendants acknowledged at oral argument that the claim language contemplates less than 100% of the drug being released in the colon. However, Defendants maintain that the amount of the release has to be close to that percentage. TR 71:14-19.

Defendants further contend that release must reliably reach near 100% release to the right side of the colon. Defendants' argument relies on language in the patent and the prosecution history, in which the patentees frequently use the term "reliable" to describe the administration of the 5-ASA. Defendants' Opening Br. at 17-18 (citing '170 patent col. 3 at 61-66) ("The Inventors have now found that 5-ASA reliably can be administered specifically to the large intestine...."); Id., col. 3 at 57-60 (distinguishing prior art that "does not provide for reliable release of 5-ASA only in

[6] While the parties' proposed constructions refer to the 5-ASA as "the drug" (Plaintiffs' Construction) or "the active ingredient" (Defendants' construction), I consider their alternate descriptions to be distinctions without a difference because the 5-ASA is the active ingredient (drug) in the invention.

the colon"); File History, 08/032,167 App., Nov. 10, 1994 Response to Final Rejection at 3 (Koh Decl., Ex. Y at WC684) (same). See also File History, 06/735,727 App., Jul. 11, 1988 Appeal Brief at 5 (Koh Decl., Ex. S at WC474) ("Applicants have discovered that 5-ASA can be reliably administered specifically to the large intestine, and especially the colon ...."). Based on the frequent usage of the term "reliable" in this fashion, Defendants reason that it is not sufficient that an occasional tablet arbitrarily releases all of its contents in the right side of the colon, but the dosage form must "reliably," i.e., almost always, release all of its contents in the colon. Defendants' Opening Br. at 18.

By contrast, Plaintiffs propose that the claim language be construed to require that "substantially all" of the 5-ASA be released. First, Plaintiffs draw the Court's attention to a part of the specification where the patentees described the claimed formulation as differing from the prior art in that "there is substantially no leaching out of the 5-ASA downstream of the colon in the normal patient." Plaintiffs' Opening Br. at 15 (quoting '170 patent col. 4 at 3-4). Based on this specification language, Plaintiffs reason that a skilled artisan would understand this to mean that the claimed formulation need not achieve perfect release to the right colon and instead may release an insubstantial amount of drug elsewhere. Id. at 15-16. Thus, Defendants' construction to impose the standard of perfection on the release, according to Plaintiffs, departs from the understanding of a skilled artisan. Id.

Plaintiffs further note that their construction is supported by extrinsic evidence. Plaintiffs' expert explained that "a skilled artisan would understand that when a

drug is formulated, variation in content, manufacturing, and performance will often lead to less than 100% of the labeled strength being released." Plaintiffs' Opening Br. at 15 (quoting Bodmeier Decl. at 35). As such, release from a dosage form is typically considered complete when "a substantial amount of drug (generally around 80%)" is released. Id. Indeed, the official specifications for drug products listed in the United States Pharmacopeia ("USP") in 1980 indicate that "release" is considered complete when a substantial amount (i.e., approximately three-quarters of the drug product) is released from the dosage form. Id. at 16 (quoting Bodmeier Decl. at 37-40). Plaintiffs additionally note that, as set forth in the description of the dissolution test specifications in the General Chapter of the 1980 USP, it was not expected that each and every tablet meet that specification. Rather, the USP anticipates that, on average, 75% to 80% of the drug will be released in the intended location. Id. (citing Bodmeier Decl. at 39).

Regarding the amount of the drug to be released, the Court finds that the phrase "substantially all" represents what the patentees intended to claim. Although the term "all" was not included in the patent itself, the Court recognizes that the patentees have repeatedly used that term during prosecution of the patent. However, in the Court's view, they did not intend the term "all" to mean 100%. To release 100% of 5-ASA to the right side of the colon would be impractical, if not impossible. Furthermore, the ordinary and customary meaning of the term in the pharmaceutical industry was, as Plaintiffs point out, the average of 80%—not 100%. Because the

term "substantially all" properly represents this consensus, the Court agrees with Plaintiffs regarding this issue.

The Court also finds, however, that the term "reliable" properly illustrates the manner in which the release of the drug was intended to occur. As Defendants correctly indicate, the term "reliable" was repeatedly used throughout the prosecution history and the specification. More importantly, it is the term "reliable" that the patentees used in pointing out the prior art's disadvantage, as well as in presenting their invention to the Patent Office, and thus to the world. See e.g., '170 patent, col. 3 at 61-66. Moreover, given that such a term implies consistency in performance, the Court agrees with Defendants that the proper construction would include the meaning of the term "reliable."

Accordingly, I construe the pertinent language of claims 1, 6, and 7 as follows:

> Whereby substantially all of the 5-ASA reliably leaves the dosage form in the ascending colon and no amount of the 5-ASA is released prior to the dosage form reaching the distal ileum.

By including the qualifiers substantially and reliably, this construction reflects that the drug will almost always be released in the colon yet the construction leaves room for the possibility that it might occasionally begin release in the distal ileum. By stating that no amount is released prior to the dosage form reaching the distal ileum, the construction makes clear that the drug may not be released upstream. As the patentees emphasized throughout the specification and prosecution history, pre-distal ileum release was replete in the prior art.

In my view, this is how a person of ordinary skill in the art would understand the above claim terms and, while avoiding the error of importing a limitation from the specification into the claim language, this construction avoids the converse evil of divorcing the claim language from the specification. This construction "capture[s] the scope of the actual invention more accurately," Phillips, 441 F.3d at 1324, than both parties' proposed constructions which reflect the all-or-nothing approach of fully embracing or rejecting dissolution and release in the distal ileum. I, further, find it unnecessary to consider the testimony of the parties' dueling experts who each offer opinions in support of their client's constructions. Because the intrinsic evidence makes the patentee's intention clear, resort to extrinsic evidence is not required but left to the Court's discretion. See Atofina v. Great Lakes Chemical Corp., 441 F.3d 991, 996 (Fed. Cir. 2006); Phillips, 441 F.3d at 1312-17. I see no need to resort to expert testimony here.

B. "Insoluble in gastric juice"

Claim language in claim 1 of the '170 patent (and, by default, the dependent claim 6) indicates that the coating used in the patentees' carrier system consists of "a layer which is insoluble in gastric juice and in intestinal juice below pH 7 but soluble in colonic intestinal juice." The parties' claim construction dispute revolves around both the meaning of "layer" and the meaning of "insoluble," although their arguments relating to these two terms are intertwined. They proposed the following claim constructions.

Claim Language	Plaintiffs' Construction	Defendants' Construction
A layer which is insoluble in gastric juice and in intestinal juice below pH 7 but soluble in colonic intestinal juice (Claim 1)	The dosage form is coated with at least one layer that has sufficient thickness so that the coating does not *fully* dissolve or disintegrate in gastric juice and in intestinal juice below pH 7, but does dissolve or disintegrate in colonic intestinal juice.	None of the layer dissolves (i.e., the layer is insoluble) in aqueous medium below pH 7 but the layer does dissolve below pH 7.5. This excludes layers containing mixtures of Eudragit S and Eudragit L.

Defendants contend that the term "insoluble" in claim 1 should be interpreted according to its ordinary and customary meaning to a person of ordinary skill in the art at the time of the invention. In support of their position, Defendants cite technical treatises in the 1980 time frame, including Pharmaceutical Sciences, wherein the term "insoluble" was defined in descriptive terms to mean no more than one part of solute dissolves in 10,000 parts of solvent. See e.g., Koh Decl., Ex. B at PAR24480. In Defendants' view, an insoluble layer will have no more than 0.01% of the layer dissolve in gastric or intestinal juices below pH 7.

Defendants further rely on language in the specification where, in describing the characteristics of copolymers used in the prior art, the patentees explained the difference between two copolymers as follows:

> Such a copolymer (available under the Registered Trade Mark "Eudragit" S) … is known to be insoluble in gastric juice and poorly soluble in intestinal juice while an analogous copolymer (available under the Registered Trade Mark "Eudragit" L) … is insoluble in gastric juice but is readily soluble in intestinal juice.

'170 patent col. 2 at 31-40. Based on this language, Defendants argue that the patentees understood that the term "insoluble," in accordance with its ordinary meaning, is the same as or less soluble than "poorly soluble," and differs in scale from "readily soluble." Defendants' Open. Br. at 8.

Defendants also emphasize the prosecution history where the patentees distinguished their claimed dosage form from other dosage forms with a coating layer containing a mixture of Eudragit S and Eudragit L in a 1984 amendment. There, the patentees explained that such a coating layer "does not in fact achieve the desired result" because such coatings would "commence disintegration" and "commence dissolution" below pH 7, whereas their claimed dosage form showed "no disintegration" below pH 7 (such as at pH 6.7 or 6.8). File History, 06/482,331 App., Sept. 26, 1984 Amendment at 8-9 (Koh Decl., Ex. F at WC372-73). According to Defendants, this prosecution history confirms that the patentees intended for the '170 patent to cover only those coatings where none of the layer dissolved below pH 7, i.e., those that did not commence disintegration and remained fully intact while in pH 7 fluids. Finally, Defendants rely on an in vitro study ("In Vitro Study") disclosed by the patentees in the prosecution history that could be read to suggest that mixtures of Eudragit S and L mixtures are disavowed.[7]

[7] "In vitro' experiments are performed in artificial environments outside living organisms (such as in a test tube or culture media), while 'in vivo' experiments are performed within living organisms." In re '318 Patent Infringement Litig., 583 F.3d 1317, 1325 (Fed. Cir. 2009).

By contrast, Plaintiffs argue that the claim language is easily understood by a skilled artisan and requires no further construction. However, should the Court determine that the language requires construction, Plaintiffs suggest that it should be construed to mean that "the dosage form is coated with at least one layer that has sufficient thickness so that the coating does not fully dissolve or disintegrate in gastric juice and in intestinal juice below pH 7, but does dissolve or disintegrate in colonic juice." Plaintiffs' Opening Br. at 17. In support of their position, Plaintiffs rely on the testimonies of both parties' experts, wherein they explain that the solubility of a coating layer must be evaluated based on the performance of the layer as a whole, not individual components. TR at 47:3-48:21; Bodmeier Decl. at 48. Because the performance of the layer will depend upon the "chemical and physical interaction" of all of the components rather than each component standing alone, Plaintiffs claim that the phrase "[n]one of the layer" in Defendants' construction is at odds with the claim language, which refers to the coating "layer" as an indivisible construct. Plaintiffs' Opening Br. at 17-18.

Plaintiffs also note that because the claim language refers to biological fluids, Defendants' construction, which is based upon in vitro performance rather than in vivo, should be given less weight in claim construction. Id. at 18. In addition, Plaintiffs point out that Defendants' construction was adopted from extrinsic evidence (in this case, technical treatises). Id. Because Plaintiffs believe that the intrinsic evidence clearly showed performance of the coating is to be judged on a functional basis, not based on an in vitro dissolution test, they argue that the Court

should not rely on Defendants' construction. Id. (citing Phillips, 415 F.3d at 1319) (extrinsic evidence is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence).

As an initial matter, the Court find its helpful to first separate out the arguments relating to the definition of the "layer." I conclude that the solubility of the layer is to be evaluated as a whole, rather than by individual components. The claim itself refers to "a layer, which is insoluble in gastric juice ...." The plain language of the claim makes clear that only one layer is anticipated hence further resort to intrinsic or extrinsic evidence is not required to construe the term.

There is one clarification required, however. At oral argument, the Court inquired whether the solubility requirement is concerned with the performance of the entire layer or whether it is focused on those elements of the layer that would prevent release of the active ingredient (the 5-ASA) to the colon. TR at 49-52. Plaintiffs agreed that the impetus underlying the claim language is to ensure that the mesalamine is released at the appropriate location in the body.

In my view, it is critical for the claim construction to take into account this clarification which gives meaning to the "release . . . to the right side of the colon" claim language. Claim 1 claims

> a layer which is insoluble in gastric juice and in intestinal juice below pH 7 but soluble in colonic intestinal juice, whereby the dosage form releases the 5-amino-salicylic-acid, salt or ester to the right side of the colon.

'170 patent, col. 10:18-20 (emphasis added). By using "whereby" the patentees made clear that the layer is designed to ensure release of the 5-ASA specifically to the right side of the colon and not before reaching the distal ileum. Hence the layer solubility requirement must be understood in this context. See Bicon, Inc. v. Straumann Co., 441 F.3d 945, 950 (Fed. Cir. 2006) ("[C]laims are interpreted with an eye toward giving effect to all terms in the claim.").

In terms of the definition of insolubility, even Defendants agreed at oral argument that the coating may dissolve in some small amount and still be considered "insoluble." See TR at 70-71. The parties disagree, however, as to what amount of disintegration is permissible under the claim language. In light of this disagreement, the Court finds that "insoluble" must be construed. Moreover, as explained in more detail herein, the Court finds that the patentees did not act as their own lexicographer and create a special definition of "insoluble" in the patent; neither the claim, the specification, nor the prosecution history specify how the term should be defined. Accordingly, the Court must determine the ordinary and customary meaning of the term.

Plaintiffs' proposed construction of insoluble, which appears below, is overbroad.

> The dosage form is coated with at least one layer that has sufficient thickness so that the coating does not fully dissolve or disintegrate in gastric juice and in intestinal juice below pH 7, but does dissolve or disintegrate in colonic intestinal juice.

Under this construction, practically any layer would be considered "insoluble" as long as at least some components of the layer remain intact below pH 7. For example, as Defendants pointed out in their opening brief, even if 95% of a coating layer dissolves, such a layer would be considered "insoluble" under Plaintiffs' proposed construction because it had not "fully" dissolved or disintegrated. And, as Plaintiffs noted at oral argument, the coating is typically comprised of additional agents, such as coloring agents. TR at 47-48. Under Plaintiffs' "fully" dissolved construction, the coating could be deemed insoluble when only the coloring agent has not dissolved. Without any objective standard to define "fully," this Court is not convinced that Plaintiffs' construction reflects the ordinary and customary meaning of "insoluble."

In addition, by stating that the "layer . . . has sufficient thickness so that the coating does not fully dissolve ....," Plaintiffs' construction suggests that the thickness of the coating determines the polymer's solubility. This is problematic because the specification treats solubility and thickness as distinct elements of the coating that, when properly combined, each helps ensure that the drug is "dumped" into the colon for topical treatment.

The specification describes the invention as "[a] solid oral dosage form . . . coated with an anionic polymer, which is insoluble in gastric juice and in intestinal juice below pH 7 but soluble in colonic intestinal juice, in a sufficient amount that the oral dosage form remains intact until it reaches the colon." '170 patent, Abstract (emphasis added). See also id. at 4:26-31 (same). By describing the polymer as "insoluble in gastric juice," the patentees made clear that solubility relates to the type

of anionic polymer that must be employed. Only after describing the type of polymer to be employed, i.e., one that is insoluble in gastric juice, do the patentees note that the dosage form must be coated with a "sufficient amount" of that polymer. Hence the "sufficient amount" language addresses how much of the polymer must be used in order to facilitate delivery of the drug to the colon.

Furthermore, the patentees distinguish the invention from the prior art by explaining that the invention "coat[s] a solid oral dosage form with a sufficient thickness of a partly methyl esterified methyacrylic acid polymer which does not dissolve in aqueous medium below pH 7 but does dissolve below pH 7.5," and that this type of coating is "entirely new in concept" because it ensures that "dissolution or disintegration does not occur until entry of the coated dosage form into the colon." Id. at 3:63 - 4:11 (emphasis added). Here, too, the patentees describe the type of polymer in terms of its solubility and separately note that the polymer must be employed in a certain thickness. Therefore, Plaintiffs' proposed construction, which focuses only on the thickness of the coating, as opposed to both the thickenss and the solubility of the polymer, is inconsistent with the specification.[8]

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[8] This reading of the specification is supported by the deposition testimony of Defendants' expert, Dr. Elder, who explains that "[a] coating does not become insoluble by making it larger or thicker; rather, solubility is an intrinsic chemical property which does not change with thickness." Elder Decl., ¶ 12. Moreover, while Plaintiffs rely on the file history statement, made in prosecution of the ancestor '386 patent application, that "[t]he requirement of coating thickness is functional, in the sense that it must be thick enough to keep the tablet substantially intact until the colon is reached but not so thick as to permit the tablet to be excreted ...." File History, 07/584,386 App., June 4, 1991 Amendment at 10 (Ainsworth Decl., Exh. M at WC532), that statement merely emphasizes that thickness can affect whether the drug is

Although Defendants' proposed construction does not suffer from the same infirmities as does Plaintiffs, Defendants' construction is problematic for a different reason. As noted, Defendants propose the construction that "none of the layer dissolves ...."[9] However, they conceded at oral argument that an insubstantial amount may dissolve. In light of this concession alone, Defendants' "none of the layer" construction must be rejected.

More to the point, neither party has pointed to any express definition of "insoluble" that is clearly set forth in the specification or the prosecution history, thus I conclude that the patentees did not act as their own lexicographer. Accord Aventis Pharma S.A. v. Hospira, Inc., 675 F.3d 1324, 1331-32 (Fed. Cir. 2012) (concluding that "patentee did not narrow the ordinary meaning of 'perfusion' . . . by either acting as its own lexicographer or disclaiming claim scope" where nothing in specification or prosecution history clearly addressed definition of that term). Where a patentee does not clearly "assign to a term a unique definition that is different from its ordinary and customary meaning," by acting as its own lexicographer, the ordinary and customary meaning of that term applies. Laryngeal Mask Co. Ltd. v. Ambu, 618 F.3d 1367, 1372 (Fed. Cir. 2010).

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released in the desired location in the digestive tract. It does not speak to the solubility of the polymer used in the coating.

[9] Defendants further seek to include in their construction a limitation excluding mixtures of Eudragit S and Eudragit L. For the reasons explained infra, I reject that limitation as unsupported by the specification and prosecution history.

Accordingly, I turn to dictionary definitions of "insoluble" to aid me in discerning the ordinary and customary meaning of that term. See Zircon Corp, v. Stanley Black & Decker,Inc., 452 Fed.Appx. 966 (Fed Cir. 2011) (considering dictionary definition where claim language is broad enough to encompass more than one meaning). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful." Phillips, 415 F.3d at 1314. Moreover, resort to scientific and technical dictionaries is appropriate where the intrinsic evidence does not define a scientific term to be construed. See Atofina v. Great Lakes Chemical Corp., 441 F.3d 991, 996 (Fed. Cir. 2006).[10] I find this circumstance to be an appropriate one for resort to a scientific dictionary definition, and turn to the definition of "insoluble" in the 1980 Pharmaceutical Sciences excerpt in the record.

The 1980 Pharmaceutical Sciences excerpt defines "insoluble" as a layer that will have no more than 0.01% of the layer dissolve. The excerpt explains that "[w]hen in pharmacopeial texts it has not been possible, or in some instances, desirable, to

[10] See also Phillips, 415 at 1318 ("Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various fields of science and technology, those resources have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention. Such evidence, we have held, may be considered if the court deems it helpful in determining 'the true meaning of language used in the patent claims.'").

indicate exact solubility, a descriptive term has been used. The following table indicates the meaning of such terms:

Descriptive terms	**Parts of solvent for 1 part of solute**
Very soluble	Less than 1
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Slightly soluble	From 100 to 1000
Very slightly soluble	From 1000 to 10,000
Practically insoluble, or insoluble	*More than 10,000*

Koh Decl., Exh. B at PAR24480 (emphasis added). See also Koh Decl., Exh. C at PAR24560 (same); id., Exh. D (British Pharmacopœia) at PAR24467 (same).

I conclude that this definition reflects the ordinary and customary definition of "insoluble" at the time of the initial application that ultimately led to the issuance of the '170 patent. I find it particularly appropriate to rely on this definition here where the definition does not contradict the intrinsic evidence of record. Compare Advanced Fiber, 674 F.3d at 1374 ("[W]e conclude that the district court erroneously construed 'perforated' using extrinsic evidence that contradicts the intrinsic evidence of record."). This definition is consistent with the definition of insoluble from the McGraw-Hill Dictionary of Scientific and Technical Terms, a scientific dictionary relied upon by the Federal Circuit in ascertaining the ordinary and customary

meaning of claim terms. See e.g.,Wavetronix LLC v. EIS Electronic Integrated Sys., 573 F.3d 1343, 1333 (Fed. Cir. 2009) (relying on The McGraw-Hill Dictionary of Scientific and Technical Terms 1159-60 (5th ed. 1994) for its definition of "local device"); L.B. Plastics, Inc. v. Amerimax Home Prods., Inc., 499 F.3d 1303, 1308 (Fed. Cir. 2007) (affirming district court's reliance on The McGraw-Hill Dictionary of Scientific and Technical Terms 2288 (6th ed. 2002) for its definition of "welding"); Atofina, 441 F.3d at 999 (citing The McGraw-Hill Dictionary of Scientific and Technical Terms 307 (4th ed. 1989) for its definition of "catalyst"). The McGraw- Hill definition of insoluble is "[i]ncapable of being dissolved in another material ...." The McGraw-Hill Dictionary of Scientific and Technical Terms 1084 (6th ed. 2002). Like the USP treatise definition, the McGraw-Hill definition makes clear that only a minute amount of the layer may dissolve.[11]

As noted earlier, Plaintiffs additionally argue that reliance on this definition is inappropriate because it reflects an in vitro dissolution standard while, in Plaintiffs' view, the specification and claims make clear that solubility is to be determined on functionally, i.e., in vivo, based on how it performs in actual gastrointestinal fluids. I reject this argument. For one, the specification refers to "aqueous medium" to describe the solubility of prior art uses of Eudragit S and Eudragit L. See '170 patent, col. 2:45-47. Furthermore, Plaintiffs relied on both in vivo and in vitro studies

[11] Moreover, while Plaintiffs urge the Court not to consult the USP treatise in defining "insoluble," Plaintiffs rely on this same treatise in support of their "substantially all" proposed construction language discussed supra.

throughout the prosecution history and, indeed, acknowledge that "*in vivo* performance may be predicted through *in vitro* tests ...." Pl. Open. Br. at 18 n.10 (emphasis in original). While Plaintiffs suggest that this reliance does not justify incorporating an in vitro standard into the claim construction, there is likewise no basis for reading into the claim an in vivo-based dissolution standard. Hence, I find reliance on the Pharmaceutical Sciences definition appropriate here.

Thus, giving the terms "layer" and "insoluble" meaning in the context of claims 1 and 6, I construe "a layer which is insoluble in gastric juice and in intestinal juice below pH 7 but soluble in colonic intestinal juice" to mean:

> a layer of which no more than 0.01% of that layer dissolves in gastric or intestinal juices below pH 7, but does dissolve or disintegrate in colonic intestinal juice.

This construction differs from Defendants' construction in that it does not require that "none" of the layer dissolve. It allows for .01% of the layer to dissolve or disintegrate. It also differs from Plaintiffs' construction in that it is more definite than "fully" dissolve. In the Court's view, this construction best harmonizes the claim language, the specification, and the prosecution history.

C. Eudragit S and L Limitation (Claims 1 and 7)

Defendants contend that the patentees clearly and unmistakably excluded layers of mixtures of Eudragit L and Eudragit S from the claimed invention, both in the specification and during prosecution. Turning first to the specification language, Defendants argue that the patentees distinguished prior art formulations having coating layers of Eudragit L alone, as well as mixtures of Eudragit L and Eudragit

S, because in all cases such coatings dissolved below pH 7. '170 patent, col. 3 at 46-49; see also id., col. 2 at 49-50 ("As far as we are aware, said mixtures [of Eudragit S and Eudragit L] invariably dissolve below pH 7."). By contrast, the patentees emphasized that their invention does not dissolve in such conditions. '170 patent, col. 3 at 61-66.

Second, according to Defendants, the prosecution history clearly disclaims the mixtures of Eudragit L and Eudragit S from claim 1. In an amendment filed on May 20, 1985, during the prosecution of an ancestor patent application (the '727 application), the patentees stated that they amended the claims "to make them more specific to the polymer used in the working examples, Eudragit S." File History, 06/482,331 App., May 20, 1985 Preliminary Amendment at 6 (Koh Decl., Exh. I at WC391). In their explanation, the patentees stated "the purpose of this characterization is to make clear that mixtures of Eudragit L and Eudragit S are excluded from the claims." Id. at 7 (Koh Decl., Exh. I at WC392) (emphasis in original). Defendants further argue that the patentees reiterated in several of the early ancestor applications that coating layers containing mixtures of Eudragit L and Eudragit S were known in the prior art, and would not achieve the desired claimed result—releasing the 5-aminosalicylic acid to the right side of the colon:

- "Applicants' own experience has revealed that mixing of Eudragit S and Eudragit L does not, in fact, achieve the desired result … capsules thus coated would probably commence disintegration on entering the duodenum which is a pH of 6.8 and will not remain intact until reaching the colon." See File

History, 06/482,331 App., Sept. 26, 1984 Amendment at 9 (Koh Decl., Ex. F at WC372-373).

- "With combinations of Eudragit L and Eudragit S, applications were still unable to achieve the desired result of capsules which reliably broke in the very distal ileum or caecum." Id. at 11 (Koh Decl., Ex. F at WC374).

- "Mixtures of [Eudragit] L + S polymers would not be suitable." File History, 06/482,331 App., In Vitro Study at 4 (Koh Decl., Ex. H at WC421) ("In Vitro Study").

- For Eudragit L and Eudragit S coating mixtures, "in all cases the coating dissolved below pH 7." File History, 06/482,331 App., Oct. 14, 1983 Amendment at 8 (Koh Decl., Ex. J at WC346) (emphasis in original).

- "A film of Eudragit L and Eudragit S in the ration 1:2 commences dissolution at about pH 6.7." File History, European Patent, Dec. 1, 1988 Declaration at ¶ 2 (Koh Decl., Ex. G at EX461, 2).

In addition, Defendants note that the patentees even submitted to the Patent Office data, i.e., the In Vitro Study, with coatings containing mixtures of Eudragit L and Eudragit S. In the study, the patentees demonstrated that in an aqueous solution buffered to a pH 6.8, either "[c]omplete disintegration" occurred or "[f]ragments remained," whereas there was "[n]o disintegration" for the coating only containing Eudragit S. In Vitro Study at 1-4. As such, Defendants believe that this is further evidence that the patentees did not believe mixtures of Eudragit L and Eudragit S would be suitable for the claimed invention. Id. at 4.

As extrinsic evidence, Defendants further indicate that Brian Evans, one of the inventors, stated during his deposition on September 17, 2009, that when even a small amount of Eudragit L was added to the coating layer, the Eudragit L would cause the coating to "dissolve slightly" below pH 7 and therefore would not be a workable formulation:

> Question: Do I take it from these initial dissolution results you ruled out any amount of Eudragit L in the formula?
>
> Answer: Yes … it was unsuitable because we wanted the product to remain intact until the distal ileum, so after looking at it in an in vitro situation we decided to - not to go ahead with it.
>
> Question: The presence of a small amount of Eudragit L would have caused the coating to dissolve slightly below pH 7. Is that accurate?
>
> Answers: Yes. What Rohm Pharma [the manufacturer of the Eudragit products] give in their literature are the various ratios you could use, and the pH ranges that they would then disintegrate in, so I took that as a guide, but did a whole range of them, so it was too early. Whatever concentration we used with the [Eudragit] L, it was going to go too early for us.

Koh Ex. E at 187:12-188:16. Based on this testimony, Defendants argue that extrinsic evidence also clearly supports their position that the patentees disclaimed mixtures of Eudragit L and Eudragit S from claim 1.[12]

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[12] The Court notes, at the outset, that it will not base its construction of the claims on an inventor's subjective intent. See Howmedica Osteonics Corp. v. Wright Medical Technology, Inc., 540 F.3d 1337, 1346-47 (Fed. Cir. 2008) ("[t]he subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim.")

Plaintiffs contend that Defendants' proposed construction is unsupported by the claim language, and should be rejected. For one, Plaintiffs argue, Defendants' reliance on prosecution history statements wherein the inventors found mixtures of Eudragit L and Eudragit S not suited for their purposes is misplaced. In the In Vitro Study, the patentees conducted a series of experiments to find the optimal coating composition for 5-ASA, using three different types of formulas. Plaintiffs especially point out that the inventors used only Formula 3, which Plaintiffs contend was comprised of a mixture of Eudragit S and Eudragit L,[13] in transit time studies as well as coating thickness studies. TR at 23:4-26:4. Based on these test reports, Plaintiffs argue that the patentees intended to claim mixtures of Eudragit L and Eudragit S. Id. Although Plaintiffs acknowledge that the report contained the statement that "[m]ixtures of L+S polymers would not be suitable," they contend that, when read in context, this statement does not give rise to the level of an express disclaimer sufficient to limit the scope of the claim.

As to the alleged disclaimer made during prosecution of the '331 application, Plaintiffs concede that the patentees amended the proposed claims early in 1985 to exclude the mixture of Eudragit L and Eudragit S. However, Plaintiffs contend that the purpose of the amendment was to limit the scope of that particular ancestor application (the '331 application). More to the point, Plaintiffs argue, the amended language in the '331 application was ultimately adopted to the '171 patent—not the

[13] More details of the composition of Formula 3 are discussed infra at ¶ 56-57.

'170 patent. Hence Plaintiffs reason that such disclaimer is only valid as to the '171 patent and that such limitation should not be read into claims of the '170 patent. Plaintiffs apply this same rationale to a similar disclaimer found in the prosecution history of the '727 application.

Plaintiffs further point to a responsive amendment made in 1995 in support of their proposed claim construction. In this amendment, the patentees explained that the reason they submitted the divisional application (which resulted in the issuance of the '170 patent) was to provide for other coatings to be used. See File History, 06/401,696 App., Nov. 17, 1995 Responsive Amendment at 4-5 (Ainsworth Decl., Exh. E at WC132-33). Moreover, there are several parts of the '170 specification wherein the patentees indicate that other polymers are also acceptable:

- "It is expected that any anionic polymer having the dissolution profile specified above can be used in the practice of the invention subject, of course, to compatibility with the relevant active agent." '170 patent, col. 4:35-38 (emphasis added).

- "Obviously, a certain amount of trial-and-error experimentation will be required before ascertaining the optimum thickness of a particular polymer on a particular solid oral dosage form but such experimentation is well within the capability of a man of average skill in the art." Id., col. 4:67-5:5 (emphasis added).

Because the '170 patent refers to non-Eudragit S polymers, Plaintiffs argue that the disclaimer of the mixture of Eudragit L and Eudragit S is not applicable to the claims of the '170 patent.[14]

While Defendants' arguments seem persuasive at first blush, it becomes clear upon reading the prosecution history as a whole that the prosecution history statements relied upon by Defendants are from ancestor applications that must be construed as applicable only to the related '171 patent which expressly excludes mixtures of Eudragit L and Eudragit S. Thus, while Defendants point to language in the prosecution history of the ancestral '727 application stating that "mixtures of Eudragit L and Eudragit S are excluded from the claims," '727 App., May 20, 1985 Preliminary Amendment, at 1-4 (Ainsworth Decl., Ex. N) (emphasis in original),[15] in the subsequent Divisional Application that resulted in the '170 patent, the patentees indicated that they were seeking broader claims than previously sought in such ancestral applications.

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[14] Plaintiffs further argue that, because they interpret the solubility limitation in claim 1 as relevant only to its performance in the body, i.e., in vivo performance, that Defendants' construction to exclude the mixture of Eudragit L and Eudragit S is erroneous. I do not address this argument because I conclude, for the reasons explained herein, that the patentees did not disclaim mixtures of Eudragit L and Eudragit S.

[15] See id. at 6 ("The Examiner lists a series of some six different expressions that are considered unjustified by the disclosure of the specification. In response to this objection, applicants have amended their claims to make them more specific to the polymer used in the working examples, Eudragit S.")

In this connection, Plaintiffs argue that the reason the patentees divided the then-pending '167 continuation application into what was ultimately issued as two separate patents was to patent the Eudragit S coating formulation through the '171 patent yet patent multiple coating formulations through the '170 patent. To support this argument, they point to a responsive amendment to the Divisional Application which states that the claims are "broad." File History, 06/401,696 App., Nov. 17, 1995 Responsive Amendment at 4 (Ainsworth Decl., Exh. E at WC132).

The Court does not find use of the word "broad" alone makes clear the patentees' intent to encompass other anoinic formulations such as a mixture of Eudragit S and Eudragit L, however, additional language in the responsive amendment supports the view that such mixtures were not excluded. The text explains that, while one of the examples in the specification teaches Eudragit S,

> [i]t is submitted that given the task of providing other coatings insoluble in gastric juice and intestinal juice having a pH below 7 but soluble in colonic intestinal juice that would release 5-ASA from the dosage form to the right side of the colon, one skilled in the art of drug composition formulation and pharmacokinetics could do so without undue experimentation.

Id. (emphasis added). Had the patentees intended to limit the scope of the '170 patent to Eudragit S coatings, there would have been no need to discuss how "other coatings" could be formulated.

Importantly, the prosecution history further suggests that the patentees envisioned the use of not just "other coatings" but other polymers containing mixtures of anionic groups. In an amendment to the 08/032,167 ancestor patent application,

the patentees distinguished the use of Eudragit coatings in the prior art by stating that "[t]here is no suggestion [in the art] that any tablet should be coated with Eudragit S coatings of the thickness (60 to 150 microns) required by the present Invention. Further, there is no reference to the use of any Eudragit coating to maintain tablets or other oral dosage forms substantially intact until the colon is reached." File History, 08/032,167 App., April 18, 1994 Amendment at 16 (Koh Decl., Exh. N at WC621). By contrasting "Eudragit S" and "any Eudragit coating," the patentees made clear that they intended to claim additional Eudragit coatings or mixtures thereof. Moreover, since the patentees subsequently limited the '171 patent to only Eudragit S coatings, their reference in the prosecution history to "any Eudragit coating" should be interpreted in the context of '170 patent to potentially include mixtures of Eudragit S and Eudragit L.

More importantly, the specification for the '170 patent explains that Eudragit S and Eudragit L are both anionic copolymers. '170 patent, col. 2:33-35. For Eudragit S, the ratio of free carboxyl groups to ester groups is approximately 1:2. For Eudragit L, in contrast, the ratio is 1:1. Consistent with this description of Eudragit S's ratio of free carboxyl groups to ester groups, the '171 patent claims include the express limitation that "said oral dosage form is coated with a . . . layer of an anionic copolymer of methacrylic acid and methacrylic acid methyl ester in which the ratio of free carboxyl groups to ester groups is about 1:2 ...." '171 patent, claims1, 9, and 12 (emphasis added). The '170 patent claims, in contrast, do not include an express Eudragit S coating formulation limitation.

For this reason, it is inappropriate to interpret the '727 ancestor patent file history statement, which incorporates Eudragit S, as limiting the '170 patent. It is better to view the statement as related to the '171 patent claims which explicitly incorporate the Eudragit S formulation. It is true that "prosecution disclaimer may arise from disavowals made during the prosecution of ancestor patent applications." Ormco Corp. v. Align Technology, Inc., 498 F.3d 1307, 1314 (Fed. Cir. 2007). But, just as "the prosecution of one claim term in a parent application will not limit different claim language in a continuation application," Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1078 (Fed. Cir. 2005), so too will prosecution disclaimers relating to claim language in an ancestral patent fail to limit different claim language in a divisional application. See Biogen, 318 F.3d at 1140 ("When the applicant is seeking different claims in a divisional application, estoppel generally does not arise from the prosecution of the parent.")

This is not to say that the prosecution history is a model of clarity. In my view, the patentees could have more precisely explained the scope of the claims they sought through the divisional application leading to the '170 patent. The Federal Circuit has noted that this sort of lack of clarity is usually because "the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation ...." Phillips, 415 F.3d at 1317. Nevertheless, courts are directed to consider the prosecution history as a whole. Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1377 (Fed. Cir. 2009) ("In determining whether there has been a clear and unmistakable surrender of subject

matter, the prosecution history must be examined as a whole.") (quoting Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1252 (Fed. Cir. 2000)). Reading the totality of the prosecution history here, and considering the Divisional Application language, I conclude that the patentees did not clearly disclaim mixtures of Eudragit S and Eudragit L for the '170 patent.

Review of the specification for the'170 patent further supports my conclusion that the patentees did not disavow mixtures of Eudragit S and Eudragit L. On the one hand, as Defendants point out, there is language disparaging mixtures of Eudragit S and Eudragit L. In discussing prior art, the specification states that "as far as we are aware, said mixtures [of Eudragit S and Eudragit L] invariably dissolve below pH 7." '170 patent, col. 2 at 49-50. The specification further states that the mixtures of Eudragit S and Eudragit L in each of the examples disclosed in the European Specification prior art "dissolved at below pH 7," which could be characteristic of Eudragit mixtures comprised in part of Eudragit L. On the other hand, the specification language states that "any anionic polymer having the dissolution profile specified above," '170 patent, col. 4 at 35-36 (emphasis added), i.e., a polymer that "does not dissolve in aqueous medium below pH7 but does dissolve below pH 7.5," id., col. 3:64-66, may be used in the coating. This statement leaves open the possibility that mixtures of Eudragit S and Eudragit L could be used should those mixtures be formulated in a manner that meets the dissolution profile. In the face of this sort of potentiality, it cannot be said that the patentees clearly disavowed all mixtures of Eudragit S and Eudragit L .

In addition, the specification language takes on a more nuanced meaning when read in context. While the specification states uncompromisingly that "as far as we are aware, said mixtures [of Eudragit S and Eudragit L] invariably dissolve below pH 7," earlier in that same paragraph the patentees explain that the mixtures of Eudragit S and Eudragit L found in the prior art were "usually employed to provide a coating of between about 25 and about 40 microns thick ...." Id., col. 2:40-42. It is clear from this preceding sentence that when the patentees state that "said mixtures invariably dissolve below pH 7," they are referring to mixtures employed in coatings of about 25 to 40 microns thick. As explained supra, the specification further makes clear that both the thickness of the coating and the type of polymer employed help ensure that the drug is delivered to the ascending colon. In this light, the patentees' seemingly absolute statement is not as clear and unmistakable as it first appears. Moreover, the Federal Circuit has made clear that criticism of a particular embodiment or technique "d[oes] not rise to the level of clear disavowal." Thorner, 669 F.3d at 1366 (quoting Epistar Corp. v. Int'l Trade Comm'n, 566 F.3d 1321, 1335 (Fed. Cir. 2009)).[16]

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[16] While Defendants cite Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mutual Pharmaceutical Co., Inc., 384 F.3d 1333, 1337 (Fed. Cir. 2004), for the proposition that critique of prior art serves as a disavowal, the Thorner Court limits Astrazeneca to its facts. Specifically, Thorner describes Astrazeneca as "limiting a patentee to particular examples of solubilizers when it stated in the specification that '[t]he solubilizers suitable according to the invention *are defined below.*" Thorner, 669 F.3d at 1366 (emphasis in original). Defendants have not pointed to similar language in the specification here.

In concluding that the patentees did not clearly and unmistakably disavow mixtures of Eudragit S and Eudragit L, I considered the In Vitro Study cited by the parties but find that an internal ambiguity renders it unhelpful. The study begins by comparing Eudragit S and L. Koh Decl., Exh. H at 1. It then sets out three formulas: Formula 1—Eudragit S only; Formula 2—a 1:2 ratio of Eudragit L to S; and Formula 3—another 1:2 ratio of Eudragit L to S. Id. at WC418-419. At the conclusion of the in vitro test results, the study states that "Mixtures of L + S polymers would not be suitable." and that "a coating of neat Eudragit-S should be capable of remaining intact ...." Id. at WC421. Thereafter, the study describes an in vivo "transit time" test involving capsules "coated with an excess of Eudragit-S (200 ml of Eudragit-S Formula 3) ...." Id. The result of this test is that "200 mls of a 3% Eudragit-S solution . . . was sufficient to protect the capsules from disintegration." Id. at WC423. Finally, the study describes a coating thickness, in vitro test designed to discover "the optimum range of acrylic coating thickness which would allow successful delivery of the dosage form to the terminal ileum/ascending colon and then to dissolve in the environmental pH thereby enabling the capsule or tablet to rapidly disintegrate." Id. The study does not state what sort of coating—Eudragit S alone (i.e., neat Eudragit S) or a mixture of Eudragit S and Eudragit L—was used.

Both the Court and the parties considered competing interpretations of the study at length during oral argument. See TR at 24-25, 61, 93-94, 106-111. Most of the confusion stems from the study's use of what appears to be two different Formula 3s. In the initial in vitro test, the authors refer to Formula 3 as a 1:2 ratio of

Eudragit L (1 g) to Eudragit S (2 g). Yet, in the in vivo transit time test results, the authors refer to Formula 3 as 200 ml of Eudragit S. Despite this ambiguity, Plaintiffs seek to rely on the results of the coating thickness test to provide context for the statement in the initial in vitro test that "[m]ixtures of L + S polymers would not be suitable." Conversely, Defendants rely on the aforesaid statement as a clear and unmistakable disavowal. In my view, with the inherent ambiguity in the study, I cannot fully discern the import and context of the "[m]ixtures . . . " statement and, consequently, do not find that it supports Defendants' argument.

In reaching my conclusion that mixtures of Eudragit S and Eudragit L are not excluded from the '170 patent, I further note the Federal Circuit's acknowledgment of the inherent difficulty in construing claims where predecessor applications or patents were drawn to narrow claims, yet claims in the successive applications are arguably broader than the invention described in the specification. See Saunders Group, Inc. v. Comfortrac, Inc., 492 F.3d 1326, 1335-36 (Fed. Cir. 2007). In addition to posing "interdependent problems of both claim construction and validity," id. at 1336, the circuit has explained that

> the problem is a difficult one, made more so by the failure of applicants to state expressly to the examiner, whether for tactical reasons or otherwise, the extent to which they intended their new claims to depart from the scope of the claims in the predecessor applications. In many such cases, as in this one, we and the district court are required to draw sometimes conflicting inferences from different sources of guidance as to proper claim construction and to weigh those conflicting inferences in reaching a conclusion as to the proper construction.

Id.

Perhaps this has been the circumstance here. While I am convinced after a thorough review of the entire prosecution history and specification that the patentees did not intend to exclude mixtures of Eudragit S and Eudragit L in the '170 patent, there are certainly aspects of the prosecution history, particularly when read in isolation, that could lead one to conclude that the mixtures were excluded. Indeed, some portions of the specification also support that view. Nonetheless, "[p]rosecution disclaimer does not apply to an ambiguous disavowal." Computer Docking, 519 F.3d at 1376. Hence, while the patentees could have certainly better clarified the breadth of the '170 patent claims, I conclude that they did not intend to narrow the claims in the manner Defendants suggests. In short, reading the claim language, the specification, and the prosecution history in conjunction, I find that there is an insufficient basis for concluding that the patentees clearly disavowed Eudragit S and Eudragit L mixtures.

D. pH Limitation for Claim 7

Claim Language	Plaintiffs' Construction	Defendants' Construction
said solid oral dosage form being coated so as to release the 5-amino-salicylic acid, salt or ester to the right side of the colon.	Substantially all of the drug leaves the dosage form in the distal part of the small intestine or the ascending colon.	The coating is insoluble below pH 7, *i.e.*, Eudragit S, and thereby reliably releases all of the active ingredient contained in the dosage form to the right side of the colon (*i.e.*, the ascending colon, and not the terminal ileum). (emphasis added)

Defendants seek to import a pH limitation into claim 7 which, on its face, does not include such a requirement. This is in contrast to claim 1 which includes that limitation, as the following comparison illustrates.

Claim 1

> 1. An orally administrable pharmaceutical composition for selectively administering 5-amino-salicylic acid, or pharmaceutically acceptable salt or ester thereof, to the large intestine, comprising a solid oral dosage form containing a pharmaceutically effective amount for the treatment of ulcerative colitis or Crohn's disease of the colon of said 5-amino-salicylic acid, salt or ester, said solid oral dosage form being coated with a layer which is insoluble in gastric juice and in intestinal juice below pH 7 but soluble in colonic intestinal juice, whereby the dosage form releases the 5-amino-salicylic-acid, salt or ester to the right side of the colon.

Claim 7

> 7. An orally administrable pharmaceutical composition for selectively administering 5-amino-salicylic acid, or pharmaceutically acceptable salt or ester thereof, to the large intestine, comprising a solid oral dosage form containing a pharmaceutically effective amount for the treatment of ulcerative colitis or Crohn's disease of the colon of said 5-amino-salicylic acid, salt or ester, said solid oral dosage form being coated so as to release the 5-amino-salicylic acid, salt or ester to the right side of the colon.

While comparison of these two claims strongly suggests that the patentees did not intend for claim 7 to contain a pH limitation, Defendants nonetheless argue that the limitation should be read into claim 7 from the specification which repeatedly references the pH solubility requirement and distinguishes prior art on that basis.

Although Defendants are correct in noting that the pH solubility requirement is one of the ways the patentees distinguished the prior art, it is not the only way. As discussed above in construing the solubility requirement in the context of claim

1, the patentees also distinguished the prior art based on the thickness of the oral dosage form coating which the patentees treated as a distinct concept in the specification. Thus, I am not persuaded by Defendants' argument that the patentees' criticism of non-pH based carrier systems (such as time-release based systems) in the prior art means that a pH limitation must be imported in all claims.

Indeed, such a conclusion would be contrary to Federal Circuit precedent that "when a patent claim does not contain a certain limitation and another claim does, that limitation cannot be read into the former claim in determining either validity or infringement." Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1326 (Fed. Cir. 2003) (internal citation marks omitted). There is a rebuttable presumption that "different claims are of different scope." Id.; In re Katz Interactive Call Processing Patent Litig., 639 F.3d 1303, 1313 (Fed. Cir. 2011).[17] Defendants have not pointed to intrinsic or extrinsic evidence sufficient to overcome that presumption here. To the contrary, the prosecution history makes clear that the patentees intended for claim 7 to be distinct from claim 1; the patentees explicitly stated in the 1996 responsive amendment in the divisional application that claim 7 differs from claim 1 in that the pH solubility requirement is absent. File History, 08/401,696 App., Mar. 13, 1996 Responsive Amendment at 3 (Ainsworth Decl., Exh. O at WC179).

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[17] While that presumption is especially strong when it relates to a dependent and independent claim, see SunRace Roots Enterprise Co., Ltd. v. SRAM Corp., 336 F.3d 1298, 1303 (Fed. Cir. 2003), the presumption is likewise applicable to two independent claims.

While the question whether claim 7 is enabled and/or invalid is a question to be resolved on another day, that claim 7 does not provide for a carrier system by which the dosage form will release to the right side of the colon raises a substantial question in the Court's mind as to whether the claim is enabled. Nevertheless, for claim construction purposes it is clear that the patentees did not intend for claim 7 to include a solubility requirement.

Defendants further point to the following prosecution history language from the same responsive amendment: "The composition of Claim [7] is embodied in the product Asacol®." Id. at 3. Defendants argue that, by using "is", the patentees intended to designate Asacol® as "the" sole embodiment of this claim—not just a preferred embodiment. As such, Defendants argue, the scope of the claim must be limited to the coating used for Asacol®, which is Eudragit S. Defendants rely on Edwards Lifesciences LLC v. Cook Inc., 582 F.3d 1322 (Fed. Cir. 2009), for the proposition that "when the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment." Id. at 1330 (quoting Chimie v. PPG Indus. Inc., 402 F.3d 1371, 1379 (Fed. Cir. 2005)).

When read in context, the aforesaid language does not support Defendants' contention that the patentees described Asacol® as the sole embodiment of claim 7 or that the patentees described Asacol® as "the present invention." In context, the statement reads:

> [T]he question presented is whether the definition of the coating as being such as to release the 5-amino-salicylic acid, salt, or ester to the right side of the colon, distinguishes [certain] Prior Art . . . The composition of Claim [7] is embodied in the product Asacol®. As indicated in the response of November 17, 1995, Laursen, et al., Gut 31, 1271-1276 (1990) describes Asacol® as tablets of 5-amino-salicylic acid coated with Eudragit S and states that most tablets have been shown to break up in the terminal ileum or ascending colon and Fig. 7 of Stolk, et al. shows that once the coating is removed from Asacol®, the 5-amino-salicylic acid (5-ASA) dissolves very quickly. . . . There is no 5-ASA held in reserve; all the 5-ASA is released. . . . It is submitted that Claim [7] distinguishes Said Prior Art combination because the provision of active ingredient release profile in an oral dosage form whereby the oral dosage form releases the 5-ASA to the right side of the colon, is unobvious.

Id. at 3-4 (emphasis in original). This passage makes clear that, first of all, the patentees were addressing the "so as to release the 5-amino-salicylic acid, salt, or ester to the right side of the colon" language—not the solubility requirement. Second, the patentees distinguished Asacol® from prior art by noting that it releases of all of the 5-ASA in the colon without holding any 5-ASA in reserve. In this context, "[t]he composition of Claim [7] is embodied in the product Asacol®" statement serves to introduce the patentees' reliance on Asacol® for illustrative purposes. Nothing in this passage suggests that Asacol® is the sole embodiment of claim 7. Thus, Defendants' reliance on Edwards is misplaced.[18]

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[18] Defendants' reliance is further misplaced because Edwards interpreted language in the specification, which is usually entitled to more weight than prosecution history statements. See Phillips, supra at 1316 (describing the specification as "the single best guide to the meaning of a claim term").

Although I reject Defendants' claim construction, I do not suggest that their argument lacks intuitive force. As I noted in connection with my analysis of the mixtures of Eudragit S and Eudragit L limitation, there are statements that, when read in isolation, support Defendants' arguments. For example, in the 1996 responsive amendment, the patentees describe Asacol® as "representing the invention." File History, 08/401,696 App., Mar. 13, 1996 Responsive Amendment at 8 (Ainsworth Decl., Exh. O at WC184). Critically, however, the patentees did not state that Asacol® was the only representation of the invention. Throughout the amendment, the patentees present Asacol® as an example, perhaps, the prime example. But there is nothing in the prosecution history language foreclosing the possibility of additional embodiments. I am further convinced of this by recalling that this responsive amendment is part of the divisional application. As explained supra, the purpose of the divisional application that resulted in the '170 patent was to secure broader claims. To read the patentees' statements narrowly would be to ignore the application of which the amendment was a part.

In this connection, I note that Defendants point to the Federal Circuit's decision in Alloc, Inc. v. International Trade Com'n, 342 F.3d 1361 (Fed. Cir. 2003), arguing that the patentees may not recapture through the 1996 responsive amendment what they allegedly disavowed early in the prosecution history and in the specification. Alloc, however, did not involve a divisional application that created a larger context within which to interpret the patentees' subsequent incorporation of broader claims. Moreover, in Saunders, supra, the Federal Circuit distinguished Alloc in a manner

relevant here. The specification in Saunders criticized prior art cylinders based on their lack of pressure seals, noting that those cylinders "typically" could not maintain adequate traction force. However, because the specification did not state that the use of pressure seals was the "only way" to maintain traction force, the circuit concluded that the specification did not support a narrowing construction. Saunders, 492 F.3d at 1333. Likewise, here, although the specification disparages non-pH-based carrier systems, the specification does not state that pH-based systems are the only means by which the 5-ASA may be released to the right side of the colon.[19]

Accordingly, I construe claim 7 consistently with the manner in which I construed claim 1, and not including the additional limitation proposed by Defendants:

> said solid oral dosage form being coated so that substantially all of the 5-ASA leaves the dosage form in the ascending colon and no amount of the 5-ASA is released prior to the dosage form reaching the distal ileum.

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[19] Alloc is further distinguishable on its facts. The patent in that case involved flooring products and methods for installing those products. In importing a limitation that there be "play" between the components of the locking joints in the flooring products, the court reasoned that the specification in that case taught "that the invention as a whole, not merely a preferred embodiment, provides for play in the positioning of the floor panels." 342 F.3d at 1369. Here, by contrast, the Eudragit S coating is a preferred embodiment. In addition, there was express language in the prosecution history describing "[t]he claimed 'play' [as] of the present invention." Id. at 1371. As noted above, no such "present invention" language is present (pun intended) here.

I reject Defendants' attempt to incorporate a solubility requirement or language limiting claim 7 to Eudragit S coatings into the construction.[20]

IV. CONCLUSION

For the foregoing reasons, the Court adoptions the following claims constructions.

Disputed Terms	Construction
A layer which is insoluble in gastric juice and in intestinal juice below pH 7 but soluble in colonic intestinal juice (Claim 1)	A layer of which no more than 0.01% of that layer dissolves in gastric or intestinal juices below pH 7, but does dissolve or disintegrate in colonic intestinal juice.
Whereby the dosage form releases the 5-amino-salicylic-acid, salt or ester to the right side of the colon (Claim 1)	Whereby substantially all of the 5-ASA reliably leaves the dosage form in the ascending colon and no amount of the 5-ASA is released prior to the dosage form reaching the distal ileum.
Whereby the 5-amino-salicylic-acid is released to the right side of the colon (Claim 6)	(same)
Said oral dosage form being coated so as to release the 5-amino-salicylic-acid, salt or ester to the right side of the colon (Claim 7)	Said solid oral dosage form being coated so that substantially all of the 5-ASA leaves the dosage form in the ascending colon and no amount of the 5-ASA is released prior to the dosage form reaching the distal ileum.

[20] Plaintiffs further argue that it would be impermissible for the Court to limit a claim to Eudragit S, a trademarked drug name. I need not address this argument as I reject the Eudragit S limitation for the reasons stated supra.

Date: June 1, 2012

/s/ Freda L. Wolfson
Freda L. Wolfson, U.S.D.J.